

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING
PHARMACY, INC. PRODUCTS LIABILITY
LITIGATION

MDL No. 2419
Dkt. No. 1:13-md-2419 (RWZ)

THIS DOCUMENT RELATES TO:

All Actions

**PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM
IN SUPPORT OF ITS PROPOSAL FOR INITIAL TRIAL SETTING AND PRETRIAL
DEADLINES FOR THE ST. THOMAS-RELATED DEFENDANTS**

Pursuant to MDL Order No. 9 [Dkt. 1425], the Plaintiffs' Steering Committee (PSC) hereby submits its Proposed Order Regarding Initial Trial Setting and Pretrial Deadlines for the Saint Thomas-related Defendants¹ (attached hereto as Exhibit A).

As required by MDL Order No. 9, the PSC met-and-conferred with the St. Thomas-related Defendants regarding putting together a proposal for bellwether trials. During those discussions, the PSC stayed true to this Court's repeated suggestion that trials in this litigation should start in 2015² – that is soon, but still it is more than three years after the deadly catastrophe occurred and the victims here were injured, more than ten months after the Court held the Rule 16 and Rule 26 conference,³ and more than eight months after the Court issued MDL Order No. 9 addressing

¹ "St. Thomas-related Defendants" or "Defendants" include: Saint Thomas Outpatient Neurosurgical Center, LLC, Howell Allen Clinic, PC, John Culclasure, MD, Debra Schamberg, RN, Vaughan Allen, MD, Saint Thomas West Hospital, formerly known as St. Thomas Hospital, Saint Thomas Network, and Saint Thomas Health.

² See January 14, 2015, Status Conf. Tr. at pp. 43-44; February 17, 2015 Status Conf. Tr. at p. 12.

³ The July 17, 2014, conference was agreed to by all parties to constitute the Rule 16 conference. See Conf. Tr. pp. 10-40.

Common Discovery.⁴ The PSC proposed a reasonable, yet expedient, plan for moving this litigation toward resolution by bringing cases to trial in December 2015. That plan is laid out in the proposed Order (the “Proposal”), attached as Exhibit A. The Proposal includes deadlines for pretrial case-specific discovery and motion practice, and outlines a process for selection of bellwether cases into a pool of potential trial candidate cases. The Proposal culminates in the first two bellwether cases being tried (or trial-ready) in December 2015.

The St. Thomas-related Defendants, on the other hand, have taken the Court’s comments about wanting trials this year as a challenge to justify why trials should not occur this year, in furtherance of their continued efforts to delay justice for the many victims of their wrongful conduct.⁵ Overall, the St. Thomas-related Defendants propose a much slower and less efficient schedule than the PSC, and one that will make it impossible to try cases in 2015 (or likely even in 2016). The Defendants’ proposal is needlessly slow and cumbersome, and contrary to the suggestions of this Court and Fed. R. Civ. P. 1.

The chart attached as Exhibit B summarizes and compares the proposals made by the PSC and the St. Thomas-related Defendants.

I. PROCEDURAL AND FACTUAL BACKGROUND

A. Early scheduling orders contemplated trials in the Summer of 2014.

This case arises from a national health tragedy caused by tainted compounded

⁴ Many of the surviving patients remain severely ill as a result of Defendants’ conduct. Wayne Reed, a plaintiff whose case is proposed by the PSC as an initial trial candidate, suffers from late-stage amyotrophic lateral sclerosis (ALS), a degenerative disease process. In fact, Mr. Reed’s counsel is separately moving this Court for an expedited trial for Mr. Reed. As this Court recognizes, for Mr. Reed and other plaintiffs in these cases, justice delayed is justice denied.

⁵ The St. Thomas-related Defendants also propose delay in the common discovery schedule, in their recently filed motion to continue the deadline for Common Issue Fact Discovery by 90 days. [Dkt. 1849]. There too, the delay is unwarranted: whatever minor resistance to discovery they are encountering can be dealt with by the Court in short order and should not require a three-month delay.

pharmaceuticals made by the New England Compounding Pharmacy d/b/a the New England Compounding Clinic (“NECC”). According to the Center for Disease Control, as a result of these contaminated pharmaceuticals at least 751 cases of confirmed meningitis or other paraspinal infection cases were reported and 64 victims have died.⁶

On February 12, 2013, the JPML consolidated for pretrial purposes all related federal actions across the country in the United States District Court for the District of Massachusetts.⁷ The cases pending in this MDL name principally three kinds of defendants: 1) NECC and its employees, owners, directors, managers, and affiliated companies (“Affiliated Defendants”); 2) vendors that provided services to NECC (“National Defendants”) and 3) the clinics and their employees, physicians, nurses, staff, and affiliated companies that injected their patients with tainted NECC pharmaceuticals (“Clinic Related Defendants”).

On Jun 28, 2013, Judge Saylor formally opened discovery against the National Defendants and the Clinic-Related Defendants while staying discovery against the Affiliated Defendants.⁸ In that same order Judge Saylor set out a timeline of events to govern cases in the MDL. That schedule contemplated trials in the summer of 2014.⁹

B. In mid-2013, the Court stayed discovery against mediating defendants.

On August 15, 2013, Judge Saylor issued his Order on Mediation Program, formally establishing the mediation program and providing a stay of discovery of any defendant that

⁶ The Court has already entered a detailed account on the factual background of this case, and as a result the PSC will limit its account of the facts to those providing context for the requested relief. *See e.g., In re New England Compounding Pharm., Inc. Prods. Liability Litig.*, 496 B.R. 256, 260-3 (D. Mass. 2013).

⁷ Dkt. No. 118.

⁸ Dkt. No. 209.

⁹ *Id.* at P. 18.

elected to participate in the program.¹⁰

On November 5, 2013, the PSC filed the Master Complaint in this action.¹¹ It named only two National Defendants, Unifirst Corporation (“Unifirst”) and Liberty Industries, Inc. (“Liberty”), because the other National Defendants had opted into the court-approved mediation program.¹² The Master Complaint also named the Clinic-Related Defendants, including the St. Thomas-related Defendants.¹³

As the cases against the Clinic-Related Defendants, including the St. Thomas-related Defendants, began appearing in the MDL as those cases completed the transfer process through the JMPL,¹⁴ the Clinic-Related Defendants immediately began requesting that Judge Saylor reconsider his previous orders on case management and specifically his orders related to opening of discovery. Significant briefing followed on proposed case management schedules.¹⁵

C. By January 2014, over eighty cases named the St. Thomas-related Defendants.

By January 28, 2014, the current structure of this MDL began to take shape. It appeared that a plurality of cases pending in the MDL named Clinic-Related Defendants – as of January 2014, there were 330 cases pending in the MDL and of those cases, 149 named a Clinic-Related Defendant.¹⁶ The overwhelming majority of these cases named

¹⁰ Dkt. No. 394.

¹¹ Dkt. No. 545.

¹² Dkt. No. 545 at P. 8-9. *See* Dkt. No. 442, ARL Bio Pharma, Inc.’s consent to join mediation program; Dkt. No. 445, Victory Mechanical Services Inc.’s consent to join mediation program

¹³ *See* Dkt. No. 545 at P. 9-19. Those clinics who had opted into the mediation program were omitted.

¹⁴ *See e.g.* Dkt. No. 456 (original notice of appearance by counsel for Saint Thomas Hospital, Saint Thomas Health, and the Saint Thomas Network – collectively the “Saint Thomas Entities”).

¹⁵ *See e.g.* Dkt. Nos. 457, 837, 838, 858, 964, 965, and 987.

¹⁶ Dkt. No. 822 (summarizing cases filed on this date).

Clinic-Related Defendants from Tennessee. Most of the Tennessee cases, 87 in all, named the Saint Thomas Outpatient Neurosurgical Center, LLC (the “Saint Thomas Clinic”) and its affiliated companies and joint venturers (the “St. Thomas-related Defendants”).¹⁷

On January 31, 2014, the PSC filed a Motion for Entry of Bellwether Trial Plan and Pre-Trial Schedule (Dkt. No. 837). The motion asked the Court to set bellwether trials to begin in May 2015, which would be approximately two-and-a-half years after news of the deadly outbreak became public and almost a year-and-a-half after this MDL was created. Like the PSC’s Proposal here, that plan included key deadlines, efficient sequencing of discovery and motion practice, a proposed process for selecting trial pool candidates, and a process for selecting bellwether trials.

On February 7, 2014, Judge Saylor recused himself and this MDL was reassigned to Judge Zobel.¹⁸ At that time, Judge Saylor had not yet established the schedule for discovery and other pre-trial matters, a task that ultimately fell to Judge Boal.¹⁹ Shortly after Judge Saylor’s recusal, Judge Boal ruled on the Plaintiff Profile Form to be used by all plaintiffs.²⁰

D. In August 2014, the Court denied the St. Thomas-related Defendants’ motions to dismiss and discovery began in earnest.

Several months followed in which the Court took up many of the motions to dismiss filed by the Clinic-Related Defendants.²¹ On August 29, 2014, Judge Zobel issued her order

¹⁷ *Id.* at p. 2. This was largely driven by the fact that Tennessee has a one year statute of limitations for personal injury actions.

¹⁸ Dkt. No. 889.

¹⁹ Dkt. No. 1425.

²⁰ Dkt. No. 923.

²¹ *See* Dkt. No. 1360.

largely denying these motions and allowing the substantive cases against the St. Thomas-related Defendants to move forward.²²

Following this order, Judge Boal, issued MDL Order No. 9, establishing the schedule regarding common issue discovery.²³ Following MDL Order No. 9, the St. Thomas-related Defendants – who up to that point had largely refused to participate in discovery – began responding to discovery requests and collecting electronically stored information pursuant to the previously issued ESI Protocol.

Despite the St. Thomas-related Defendants delaying discovery for many months by refusing to participate in common discovery and filing a motion to stay discovery – based on the pedantic position that the Court had not yet conducted a Rule 26(f) conference (*see* Dkt. Nos. 595, 598) – the parties have now made significant progress on common discovery. The parties have exchanged paper discovery on common issues; Plaintiffs have provided detailed Plaintiff Profile Forms, including providing releases for medical records; Plaintiffs have taken three depositions of principal witnesses associated with the St. Thomas-related Defendants, with additional common issues depositions set for the coming days and weeks; and Defendants have served third party subpoenas and requests for depositions.

II. GUIDING PRINCIPLES OF THE PSC’S PROPOSAL

Applying fundamental principles of aggregate litigation, in light of the circumstances of these cases, the Proposal is premised on the following principles:

²² *Id.*

²³ Dkt. No. 1425. A “common issue” is defined as “an issue that pertains to all or a substantial number of cases in the MDL.

- Rule 1 of the Federal Rules of Civil Procedure frames the entirety of procedural due process in federal civil litigation, directing that the Rules be employed to secure the just, speedy, and inexpensive determination of the actions centralized in this proceeding. Fed. R. Civ. P. 1.
- Given the number of fatal and severe, life-changing injuries at issue in this MDL, and given that some defendants have limited assets and insurance coverage with which to pay for any harm they allegedly caused, the parties must conduct this litigation with particular efficiency and economy.
- The Court and the PSC have expressed an intention that cases that are not in a mediation program – either the program established by this Court or some through other private mediation – should be moved through discovery and readied for trial as soon as practicable.

In view of these guiding principles, the PSC's Proposal seeks to balance the rights and concerns of the impacted parties. The Proposal also seeks to maximize the efficiencies available in MDLs to develop for the parties the information they need to assess the potential avenues for resolving the cases, whether through motions, trials, or settlement.

Finally, the Proposal efficiently prioritizes by seeking only to set a pretrial and initial trial schedule for bellwether cases naming the St. Thomas-related Defendants.²⁴ The St. Thomas-related Defendants are the logical first choice for the first trials in this matter, for a number of

²⁴ At the same time, the PSC is also working to move forward efficiently against other Clinic-Related Defendants, and thus is filing, contemporaneously with this motion, a motion to amend MDL Order No. 9 to address pretrial schedules for the Premier and Box Hill related defendants, as well as temporarily staying the deadlines for completing common discovery against those clinic and doctor defendants with five or fewer filed actions currently pending against them in the MDL (but not the deadline for completing discovery from the settling or national defendants).

reasons. First, the St. Thomas-related Defendants are the Clinic-Related Defendants with the most cases pending against them. Second, Plaintiffs' claims against these entities have already withstood extensive briefing on motions to dismiss. Third, and more importantly, significant discovery has been completed and is scheduled against these entities, including significant document production, written discovery, and depositions; thus discovery of the St. Thomas-related Defendants is farther along than that of any other Clinic-related Defendants.

III. KEY FEATURES OF THE PSC's PROPOSAL

The Proposal sets forth in detail the sequence and deadlines for conducting the litigation against St. Thomas-related Defendants. We highlight several key features of the PSC's Proposal here.

The first step in the Proposal is selection of Initial Trial Pool Cases. Within ten days of the date of the order, Plaintiffs and the St. Thomas-related Defendants are each to select four Initial Trial Pool Cases, which will be their candidates for individual trials. Proposal ¶ I(A).²⁵ Out of that pool, the Court would eventually select the first two bellwether trial cases.

In the event that the same case appears on both parties' lists, those cases will be tried, and the parties will select additional cases so that the Initial Trial Pool includes eight cases. Proposal ¶ I(C). Additional cases will be added to the pool in the following manner: The PSC shall choose an additional case for the oldest duplicate case (based on original filing date); the next duplicate case by the Defendants, and so on in alternating turns until all duplicates have been resolved and a full list of eight cases has been created. *Id.*

²⁵ Only cases involving (i) administration of NECC's methyl prednisolone acetate (MPA) and (ii) fungal meningitis or other fungal infections are eligible to be selected as Initial Trial Pool Cases. Plan ¶ I(D). Non-MPA cases may be the subject of a later bellwether process, should any such cases remain in the MDL and if there is a precedential benefit to a bellwether process for such cases.

If any Initial Trial Pool Cases is settled or dismissed for any other reason, with or without prejudice, a replacement Initial Trial Pool Case shall be selected by the non-moving party.

Proposal ¶ I(E). For example, if Defendants choose to settle a case, Plaintiffs select its replacement. If Plaintiffs voluntarily dismiss a case, Defendants choose its replacement. *Id.*

No later than 15 days after this Order is entered, the parties shall file a Notice of Position on Venue and *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998).

Proposal ¶ I(B). As indicated in prior briefing, Plaintiffs are prepared to waive *Lexecon* and allow their cases to be tried before this Court for the purpose of expediting trial and avoiding further delay in the resolution of their cases. Alternatively, in the event that the St. Thomas-related Defendants do not choose to waive *Lexecon*, Plaintiffs propose that Judge Zobel be appointed temporarily to sit in the Middle District of Tennessee pursuant to 28 U.S.C. 1407(b), in order to try these cases.

After the eight Initial Trial Pool Cases are selected, the parties would conduct case-specific discovery in those cases only, which would include depositions of parties regarding case-specific issues, and depositions of other treating health care-providers. Proposal ¶ I(F). All Case-Specific fact discovery for Initial Trial Pool cases shall be completed by August 1, 2015. *Id.*

After case-specific discovery is completed, and by August 15, 2015, the parties will propose to the Court the sequence in which the Initial Trial Pool cases should be tried, along with an explanation supporting their proposed trial sequence. Proposal ¶ II(A). By September 1, 2015, the Court will select the order in which the Initial Trial Pool Cases will be tried and/or remanded,

designate the first two cases to be tried and/or remanded (the “First Two Trial Case Picks”).

Proposal ¶ II(B).

In the first two trial cases only, the parties would conduct case-specific expert discovery, including providing Rule 26 disclosures and reports, as well as depositions on case-specific issues. Proposal ¶¶ III(A)-(C). The Proposal also sets forth deadlines for motions in limine, motions to limit expert testimony, and case-specific dispositive motions. Proposal ¶¶ III(D)-(G).

The two initial trial cases will be trial-ready by December 14, 2015. Proposal ¶ IV(A). Dates for future trials of Initial Trial Pool Cases will be set by separate order(s). Proposal ¶ (IV)(B).

IV. THE DEFENDANTS’ PROPOSAL IS NEEDLESSLY CUMBERSOME AND SLOW

The chart attached as Exhibit B summarizes and compares the PSC’s Proposal with the proposals made by the St. Thomas-related Defendants. Overall, the St. Thomas-related Defendants propose a much slower and less efficient schedule than the PSC, and one that will make it impossible to try cases in 2015 (or likely even in 2016). The Defendants’ proposal is needlessly cumbersome and slow, and thus is contrary to the suggestions of this Court and requirements of Rule 1.

For example, the Defendants’ proposal unnecessarily complicates the process by proposing a too-large Initial Trial Pool. The St. Thomas-related Defendants would have the parties choose a total of 16 or even 20 cases for the Initial Trial Pool, while the PSC would have the parties choose only eight total. The PSC’s proposal makes more sense, though, because choosing eight cases creates a more manageable Pool, and avoids any reason to stage (or delay) Case-Specific discovery, as the St. Thomas-related Defendants have proposed. Having only eight

cases in the Pool thus streamlines the case-specific discovery process so that it can be completed by August 1, 2015, as indicated in the PSC's Proposal. Further, PSC's Proposal would focus on initial trials for cases involving administration of MPA and fungal meningitis or other fungal infections, which promotes efficiency because most of the cases involve the administration of MPA, and the most significant injuries are injuries and deaths caused by fungal infections – thus these cases will have the most predictive value, an important characteristic of good bellwether cases.

The St. Thomas-related Defendants also propose a needlessly slow and drawn-out schedule. In part, this is because of the unnecessary complexity of their proposal. But the St. Thomas-related Defendants' schedule also adds in pointless delay that has nothing to do with the cumbersome nature of its proposal. For example, right off the bat, the Defendants propose an unnecessarily long time for the parties to exchange their Initial Trial Pool selections – up to 30 days after the entry of the Court's order setting the schedule, in contrast to the PSC's proposed 10 days. The PSC's ten-day timeframe is particularly reasonable and sufficient given that the individual discovery needed for defendants to prepare a case for trial has already largely been completed,²⁶ and the parties have already gone through the process of selecting potential trial

²⁶ Under MDL Order No. 9, plaintiffs were required to produce extensive Plaintiff Profile Forms and 5 record releases to the defendants by November 17, 2014, meaning the St. Thomas-related Defendants have been in possession of profile forms and relevant records releases for the plaintiffs for over six months. In fact, plaintiffs in Tennessee also served these defendants with pre-suit notice providing a HIPAA release for medical records even before filing suit, so these defendants have been able to access relevant medical records from the plaintiffs for, in some instances, three years. Whatever additional discovery necessary to try the proposed cases in December 2015 can be completed in the summer of this year, as indicated in the PSC's proposal.

pool case picks earlier this year, in the context of the PSC's motion for expedited trial.²⁷ [Dkt. No. 1716.] Thus selecting eight Initial Trial Pool cases from those the parties had already selected for this purpose earlier this year should not require more than ten days.

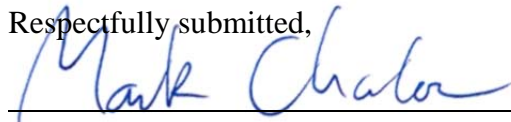
The schedule proposed by the PSC is intended to get two cases trial-ready by December 2015 – three years after most of the plaintiffs were injured or killed and over two years after this MDL was created. There is nothing about this timetable that is unusual or prejudicial to defendants. On the contrary, the interminable delay advocated by defendants is unfairly prejudicial to plaintiffs in that it would excessively delay justice.

V. CONCLUSION

To move this litigation forward, in accordance with the mandates of Federal Rule of Civil Procedure 1 and the suggestion of this Court that trials should begin this year, the PSC respectfully requests that this Court enter the attached proposed order adopting the PSC's proposed initial trial schedule.

Dated: May 18, 2015

Respectfully submitted,

A handwritten signature in blue ink, appearing to read "Mark Chalos", is written over a horizontal line.

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²⁷ See Dkt. No. 1771, indicating that by April of this year, the PSC had selected six proposed candidates for the initial trials against St. Thomas-related Defendants and the defendants had proposed nine cases as initial trial candidates.

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CERTIFICATE OF SERVICE

I, Annika K. Martin, hereby certify that I caused a copy of the foregoing and Exhibits A and B to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

Dated: May 18, 2015



Annika K. Martin